UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,258	07/21/2005	Min-Ho Shong	20050-00003	2722

7590 07/30/2007

JHK Law
P.O. Box 1078
La Canada, CA 91012-1078

EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,258	SHONG ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *6 and 11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received on May 8, 2007 from Joseph Hyosuk Kim, the election with traverse of group I, claims 1-5 (in part) and claims 7-10 (in part), is acknowledged.

The Applicant traverses on the grounds that Stiens et al do not teach transformed plants, Whitelam does not teach hTSHR, and there is no suggestion or example of expressing hTSHR in plants (see page 3 of the response). This is not persuasive, however, because it would be obvious to utilize the methods taught by Whitelam to express the recombinant protein taught by Stiens (see rejection under 35 USC 103, below), and therefore the claimed invention lacks an inventive step. Because it lacks an inventive step, it does not have a special technical feature as defined by PCT Rule 13.2.

The Applicant further argues that the inventions of groups I-IV are closely related and there is not a serious burden to search and consider all of the claims (see paragraph bridging pages 3-4 and second paragraph on page 4 of the response). This is not persuasive, however, because the restriction is based on lack of unity rules, and therefore, there is no need to demonstrate a burden to justify restriction.

Furthermore, although burden is not an issue under lack of unity rules, it would nevertheless constitute a burden to search for the extracellular domain in addition to searching for hTSHR.

The restriction requirement is proper and is MADE FINAL.

Specification

2. The specification is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. On page 12 in line 9 there is an embedded link. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP 608.01.

3. The use of the trademark TWEEN has been noted in this application. It should be written in all capital letters wherever it appears; or alternatively, it should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Applicant is advised that should claim 5 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitelam (J. Sci. Food Agric. (1995) Vol. 68, pp. 1-9) in view of each of Stiens et al (Biotechnol. Prog. (2000) Vol. 16, pp. 703-709), Mullins et al (J. Clin. Invest. (1995) Vol. 96, pp. 30-37), and Takeo et al (EP 0 719 858 A2 (1996)).

The claims are drawn to a method of producing human thyroid stimulating hormone receptor (hTSHR)

Whitelam teaches the production of recombinant proteins in plants, including the use of an *Agrobacterium tumefaciens* binary vector system to transform tobacco

plants, which are *Nicotiana tabacum* (see page 3, left column). Whitelam teaches the use of the CaMV 35S promoter which functions in plants (see page 3, left column). Whitelam teaches purification of a recombinant protein from a transgenic plants (see page 2, right column). Whitelam teaches that mRNA from a transgene was produced in the plant (see third paragraph on page 6) which indicates that the construct comprised a functional polyadenylation signal. Whitelam teaches the selection of a stable transgenic line (see second paragraph on page 4), and the steps of selecting transformed plant cells and regenerating a plant from said cells in order to generate a stable transgenic line are necessary steps that are well-known in the art and are required in order to generate a stable transgenic plant, therefore they are in intrinsic part of the method taught by Whitelam.

Whitelam does not teach recombinant hTSHR.

Stiens et al teach recombinant hTSHR produced in human leukemia cells (see last paragraph on page 704). Mullins et al teach recombinant hTSHR produced in B-cells (see right column on page 31). Takeo et al teach recombinant hTHSR produced in a myeloma cell line (see abstract).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to utilize the methods taught by Whitelam to produce the hTSHR taught by Stiens et al, Mullins et al or Takeo et al. One would have been motivated to do so because Takeo et al, Stiens et al, and Mullins et al teach that recombinant hTSHR has commercial value for use in

diagnostic tests (see Takeo, column 1, lines 43-51; and Stiens, second paragraph, left column; page 703; and Mullins, first paragraph, page 30). Given the successes of Stiens et al, Mullins et al, and Takeo et al in producing recombinant hTSHR and given the successes of producing other recombinant therapeutic proteins in transgenic plants taught by Whitelam, one of ordinary skill in the art would expect to succeed in expressing hTSHR in transgenic plants.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references; especially in the absence of evidence to the contrary.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER